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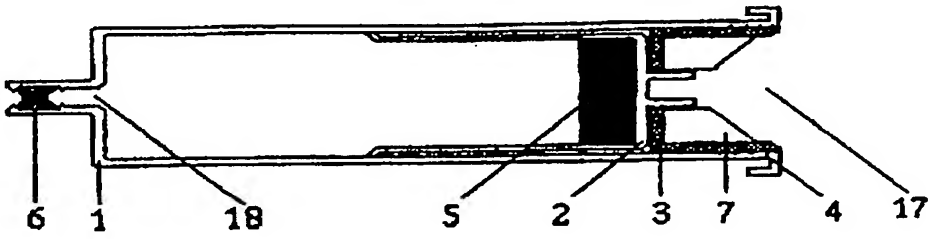
(54) Title: BLOOD COLLECTION, PLASMA SEPARATION, AND HIGH PRECISION PLASMA DISPENSING DEVICE

(57) Abstract

The device consists of a syringe (1) with a plunger designed as a cup (2) large enough to contain a plasma separating thixotropic gel (5) and all the heavier parts of the blood. By centrifugation the gel plug has moved to cover the heavier parts of the blood, which is trapped in the plunger (2), leaving the plasma free in front to be dispensed from the syringe by advancing the plunger (2).



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Blood collection, plasma separation, and high precision plasma dispensing device.

FIELD OF INVENTION

This invention relates to an apparatus and a method for collecting a multiphase fluid such as blood and for separating and partitioning said fluid into a lighter phase and more particularly to blood collection in milliliter quantities, to plasma separation by centrifugation and to high precision plasma dispensings in microliter quantities.

BACKGROUND

Specimen collection and specimen handling is an area of very high cost, because it is very labour intensive. It is also prone to error. It subjects workers to biohazards from infectiuous agents which contaminate blood and is the area which at present is considered to be in greatest need of technological innovation and improvement.

PRIOR ART

It is clear that the solutions to many of the problems associated with specimen handling are robotisation and automation, however, presently used manual or robotic, automated or computer-controlled liquid handling and metring devices (pumps, pipettors and dilutors) are not very well adapted to robotic handling. Traditional automatically controlled liquid metering devices are heavy complex mechanisms, using reciprocating pistons in syringes connected to motor driven valves. These valves are connected to liquid reservoirs via liquid carrying tubing and to sampling and delivery tips that are manipulated by robotic arms. The very high cost and complexity of such devices and the neressity for tubing carrying liquids

requires that the same pump is usedfor many different liquids, bloodsamples, standards, diluents and reagents. This in turn leads to problems of carry-over and cross-contamination, further complicated by the necessity for washing (and wiping) sampling and dispensing tips before they can be introduced into any new liquid such as blood samples. standards or reagents. Rinsing and washing stations, rinsing liquids. tubing, pumps and collection reservoirs for rincing liquids, all enlarage contaminated territory, as well as adding to the size, cost and complexity of the structure. This also adds maintenance work on potentially contaminated material and increases operating costs and biohazards for the personnel. Often blood samples are received in the laboratory in tubes provided with a rubber stopper and identification marks. The liquid level of the plasma and the level of the heavier parts of the blood varies from tube to tube, for that reason traditional robotic liqid handling stations in the laboratory must be provided with expensive liquid level sensing devices for proper positionig of sampling tips. Removing the rubber stopper is the first step in a chain of manipulations which constitute bio-hazard risk. In many cases manual or robotic distribution of aliquots of samole are done into open containers or cups, that in turn are to be distributed to different analysis stations. In these and similar operations the direct identification with the original label on the received sample tube is not always positively secured.

OBJECT OF THE INVENTION

improved blood specimen collection, plasma separating and plasma dispensing device avoiding the aforementioned drawbacks.

It is a further object of the present invention to provide an an integral specimen collection and plasma dispensing device that easily and costeffectably can be handled by robotic manipulation, thus permitting and simplifying total automation of specimen handling.

It is a further object of the present invention to provide a plasma dispensing device that easily and safely can be handeled manuelly.

It is a further object of the present invention to provide an integral blood specimen collection, plasma separating and plasma dispensing device, that is low in cost and disposable.

It is a further object of the present invention to compleatly eliminate the transfer of the original sample from the original collection device for delivery of precise quantities of plasma in the volume range required by clinical chemistry analysis, thereby eliminating many of the problems in prior art devices described earlier.

It is a further object of the present invention to compleatly eliminate the need for liquid level sensing devices in dedicated analytical instruments or robotic workstations.

It is a further object of this invention to provide a plasma dispensing device that compleatly eliminates cross contamination.

It is a further object of this invention to guarantee positive identification of every plasma dispensing performed, by the fact that the dispensing is done by the one and same original device as it was collected in.

It is a further object of this invention to reduce the biohazard to tersonnel in the laboratory, by the fact that the sample is kept in and manipulated and translocated in a closed container.

SUMMARY OF THE INVENTION

In accordance with these and other objects are accomplished by an apparatus as outlined in claim 1 a preffered embodyment of the invention the integral specimen collection, plasma separation and high precision plasma dispensing devise consists of a syringe with a plunger designed as a cup and beeng provided with a ring shaped part with a self tapping screw working in the syringe when rotated. said cup is large enough to contain a plasma separating thixotropic gel and all the parts of the blood heavier then the plasma. The ring shaped part on its back side may have spoakes for engagement to turning devises. The syringe is evacuated, and it is filled like any other known evacuated specimen collection tube through a rubber stopper. The plasma separation is performed by centrifugation of the syringe. The heavier parts of the

blood is trapped in the plunger behind the gel plug, which by force created by centrifugation has moved from the bottom of the cup towards its top, thus leaving the plasma in front of the plunger free to be dispensed from the syringe when the plunger is advanced. Plasma dispensing is done through dispensing device after penetrating the rubberstopper. The size and the high precision of the volume dispensed may be controlled by the angular movement of the plunger, which works as an internal micrometer screw inside the syringe.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig 1 shows a cross section of the evacuated blood collection device empty except for a volume of thixotropic gel at the bottom.

Fig 2 shows a cross section of the device equiped with a needle and filled with blood.

Fig 3 shows a cross section of the device after centrifugation.

Fig 4 shows a cross section of the devise equipped with a delivery tip.

Fig 5 shows the device of Fig 1 providec with a linearly movable plungerrod 19.

DETAILED DESCRIPTON OF THE DRAWINGS.

Refering to fig 1 of the drawings, that shows a cross

section the blood-collection device unfilled, it will be seen that the device consists of a plastic syringe 1 equipped with a plunger 2 that is shaped like a deep cup. This cup is pressfitted into an other plunger 3, which is equipped with a self tapping scew thread 4 threading the syringe 1. The plunger-cup 2 is partly filled with a gel-like thixothropic agent 5 of the type in common practise to separate the plasma from the rest of the blood. The syringe is provided with a rubber stopper 6. The plunger 3 is equipped with blade-like radially oriented spoakes 7 for engagement to turning devices.

Refering to fig 2 of the drawings which showes the blood-collection device equipped with a hypodermic needle 8 fitted onto a valve containing adaptor 9 (eqiped with a needle 10) for multiple prelevment of a type used in common praxis by the profession. The needle 10 is shown penetrating the rubberstopper 6. The syringe is filled with blood 11.

Refering to fig 3 of the drawings which shows the syringe with the needle 8 and adaptor assembly 9 of fig 2 removed. It also snows the rearrangement of the content of the syringe after an appropriate time and speed of centrifugation. The gel-like agent 12 separates the plasma 13 free from the heavier parts of the blood 14 trapped inside the plunger cup 2 behind the gel plug which has moved from the bottom of the cup towards the top.

Refering to fig 4 of the drawings which shows the syringe 1

equipped with with a plastic tip 15 fitted onto a dispensing device 9 whose needle 10 penetrates the rubber-stopper 6. 16 indicates the thread tapped in the plastic body of the syringe 1 by the rotated part 3, which is shown advanced to a new position with reference to its position in fig 3.

Refering to fig 3 of the drawings, that shows the device of fig 1 provided with a linearly movable plunger rod 19.

CLAIMS:

1. An apparatus for collecting a multiphase fluid such as blood and for separation and partitioning said fluid into a lighter phase and a heavier phase, comprising
a syringe (1) being open at one end (17) and having an opening (18) at the other end for recieving a hypodermic needle (8) or a dispensing device respectivly , a plunger (2) being shaped like a cup and being partly filled with gel-like thixotropic agent (5).

2. The apparatus of claim 1, wherein said syringe (1) is evacuated and said opening (18) at said other end is provided with a rubber stopper (6).

3. The apparatus of claim 2, wherein means (3,4) are provided to prevent said plunger (2) from moving into said evacuated syringe (1).

4. The apparatus of claim 3, wherein said means consists of a ring shaped part (3), said part being pressfitted into said plunger (2) and being provided with a self-tapping screw (4).

5. The apparatus of claim 4, wherein said ring shaped part (3) is provided with engagement means (7) for rotating said part (3).

6. The apparatus of claim 5, wherein said ring shaped part (3) is provided with spokes (7) for engaging motoric means.

7. The apparatus of claim 1, wherein means (19) is provided for moving said plunger (2).

8. The apparatus of claim 1, wherein said plunger (2) is provided with a sealing lip (20) around its open end.

9. A method for collecting a muliphase fluid such as blood and for separating and partitioning said fluid into a lighter phase and a heavier phase and for dispensing said lighter phase onto a sample means, such method comprising the steps of
sucking said fluid into a syringe according to claim 1,
centrifugating said fluid in said syringe,
dispensing said lighter phase from said syringe onto said sample means.

10. The method of claim 9, wherein said dispensing step is accomplished by motoric means.

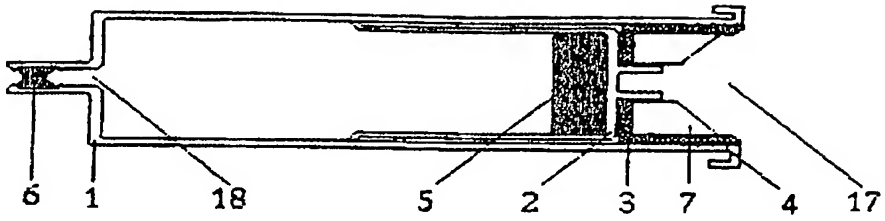

Fig 1

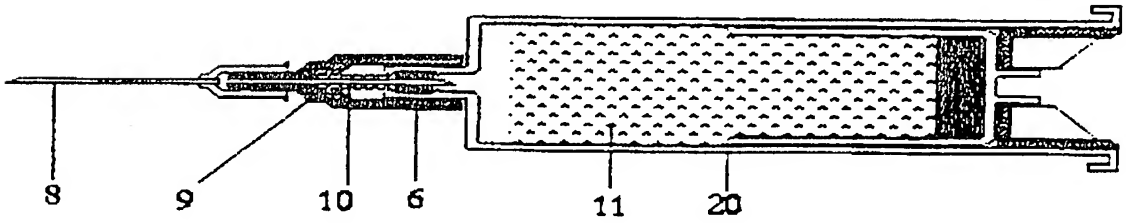

Fig 2

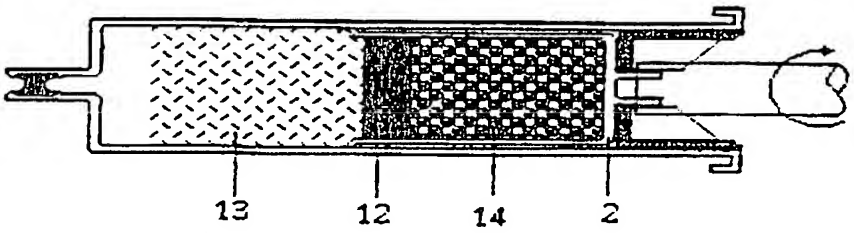

Fig 3

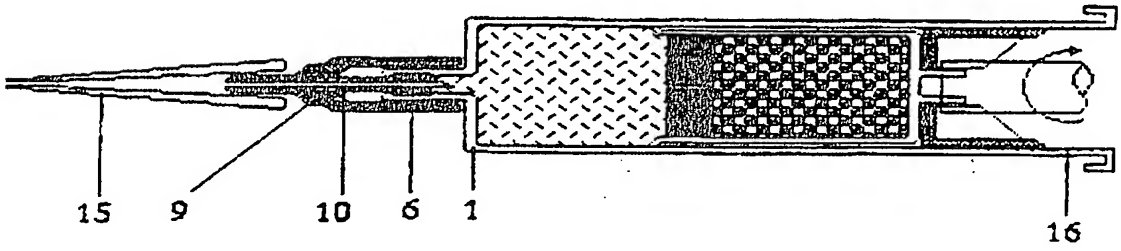

Fig 4

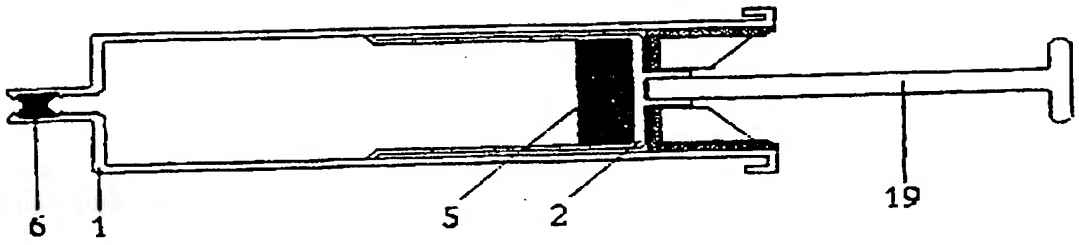

Fig 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00952

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/14, A61M 5/315
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9100114 A1 (ULTRADENT PRODUCTS, INC.), 10 January 1991 (10.01.91), figures	1-10
A	EP 0363485 A1 (TERUMO KABUSHIKI KAISHA), 18 April 1990 (18.04.90), page 7, line 15 - line 20, figure 1	1-10
A	WO 9002516 A1 (SAFE-TEC CLINICAL PRODUCTS, INC.), 22 March 1990 (22.03.90), page 17, line 12 - line 27, figure 3	1-10
A	US 3886928 A (WALTER SARSTEDT), 3 June 1975 (03.06.75), page 7, line 13 - line 21, figure 9	1-10

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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21 December 1995	22 -12- 1995
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0265876 A2 (HABLEY MEDICAL TECHNOLOGY CORPORATION), 4 May 1988 (04.05.88), column 3, line 34 - line 53, figures 1,2	4

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INTERNATIONAL SEARCH REPORT

Information on patent family members

11/12/95

International application No.
PCT/SE 95/00952

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